

Notice of Allowability

Application No.

10/500,532

Applicant(s)

RAJAMANNAR ET AL.

Examiner

Sabiha Qazi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/5/06.
2. ☒ The allowed claim(s) is/are 1-3,5-22,41,42,44,45 and 47.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413) (2) Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Mark Pohl on 6/29/06.

The application has been amended as follows:

Claims 1, 3 and 45 are amended as follows:

Claim 1's "b)" will be amended. Delete these terms: " the desmethylocitalopram impurity viz., 1-[3-(methylamino)propyl]- 1-(4-fluorophenyl)-1,3- (dihydro-5-isobenzofuran carbonitrile," after "containing". Also, delete "the amide impurity viz. 5-carboxamide-1-(3-dimethylnminopropyl)-1-(4-fluorophenyl)-phthalide" after "a compound of formula 3, and"

Claim 3 will be amended. Delete these terms: "the desmethylocitalopram impurity viz. 1-E3-tmethylnminolpropyll-1-(4-fluorophenyll- 1,3- (dihydro-5-isobenzofuran carbonitrile" after "...the crude compound of formula 1, containing...". Also delete: "and the amide impurity viz. 5-carboxamide -1-(3-dimethylaminopropyl)-1-(4-fluorophenyl)-phthalide," after "...a compound of formula 3"

In claim 45 a typing error "in ^ claim^ 1^," has been corrected to read "in claim 1,"

Claims 1 and 3 will after amendments read as follows:

Claim 1's amended portion should now read: "b) treating the resultant crude compound of formula 1 obtained in step a) containing a compound of formula 3, and a compound of formula 4..."

Claim 3's amended portion should now read: "...with substantially low levels of impurities, comprising treating the crude compound of formula 1, containing a compound of formula 3, and a compound formula 4."

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

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Claims 1-3, 5-22, 41, 42, 44, 45, and 47 are allowed. The instant invention is drawn to a process for the preparation of citalopram of formula 1. Closest prior art is WO 00/11926, which discloses method for the preparation of citalopram.

The prior art does not teach nor fairly suggest:

- a. The reaction of the compound of formula 2 with a cyanide source which requires the presence of an iodide
- b. The instant claims require cyanide reversal agent, phosphorous oxyhalides, and phosphorous oxides
- c. Examples 1-5 (pages 24-26 of the Specification) disclose the improved purity when the cyanide exchange reaction is carried out in presence of an iodide. The Specification examples provide data showing preparation of citalopram of purity > 94%
- d. Tables II and III also show the advantages in presence of an iodide

Examiner thanks Attorney Mark Pohl, Esq. for his cooperation during the prosecution of this application.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D
PRIMARY EXAMINER

Friday, June 30, 2006